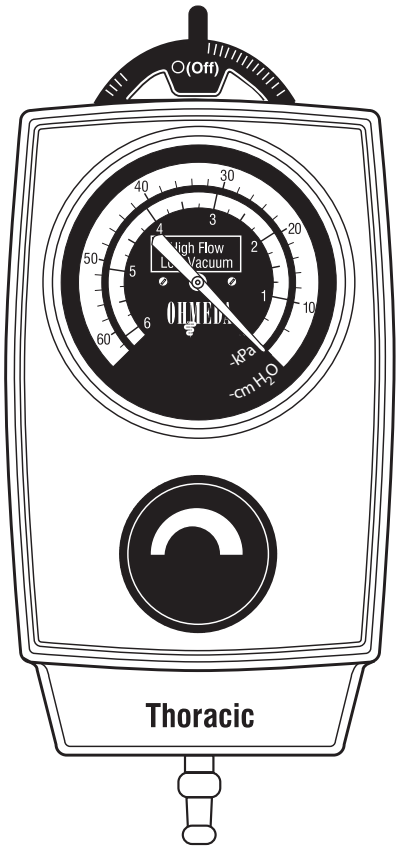
Ohio Medical Corporation™

Thoracic Vacuum Regulators

Instructions for Use



User Responsibility

WARNINGS ⚠ **This device is to be used only by persons who have been adequately instructed in its use.**

⚠ **Do not use this device in the presence of flammable anesthetics. Static charges my not dissipate and a possible explosion hazard exists in the presence of these agents.**

This Product will perform in conformity with the description thereof contained in this operating manual and accompanying labels and/or inserts, when assembled, operated, maintained and repaired in accordance with the instructions provided. This Product must be checked periodically. A defective Product should not be used. Parts that are broken, missing, plainly worn, distorted or contaminated should be replaced immediately. Should such repair or replacement become necessary, Ohio Medical recommends that a telephone or written request for service advice be made to the nearest Ohio Medical Regional Service Center. This Product or any of its parts should not be repaired other than in accordance with written instructions provided by Ohio Medical and by Ohio Medical trained personnel. The Product must not be altered without the prior written approval of Ohio Medical's Quality Assurance Department. The user of this Product shall have the sole responsibility for any malfunction which results from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than Ohio Medical.

AAA A 12345

This alpha character indicates the year of product manufacture and when the serial number was assigned; "Y" = 1995, "Z" = 1996, "A" = 1997, etc. "I" and "O" are not used.

CAUTIONS ⚠ Only competent individuals trained in the repair of this equipment should attempt to service it.

⚠ Detailed information for more extensive repairs is included in the service manual solely for convenience of users having proper knowledge, tools and test equipment, and for service representatives trained by Ohio Medical.

⚠ Not for field or transport use.*

* The categories of Field and Transport Use are specifically defined in ISO 10079-3 (BS 7259: Part 2) "Field" means accidents or emergencies outside the hospital. "Transport" means use in ambulances, cars and airplanes. These situations may expose the equipment to uneven support, dirt, water, mechanical shock and temperature extremes. Ohmeda suction equipment has not been tested to comply with the specific requirements of these categories.

Definitions

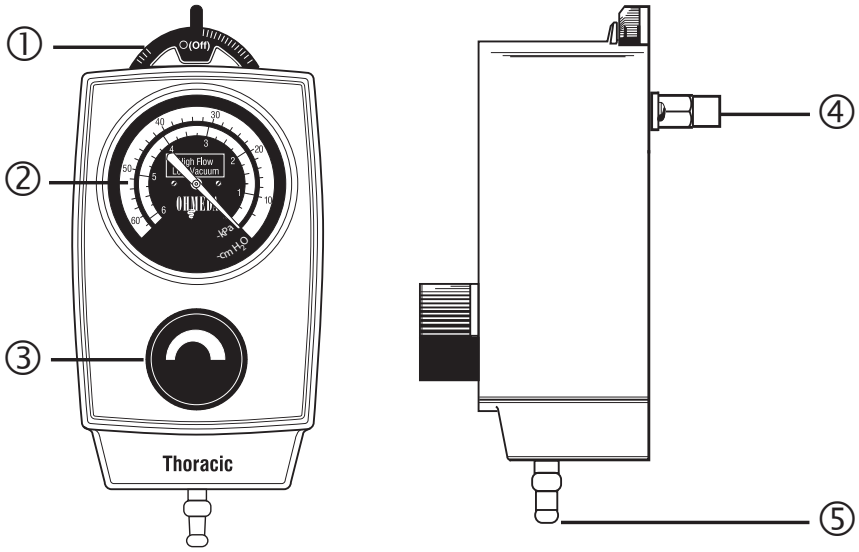
WARNING	= possible injury to patient or operator
CAUTION	= possible damage to equipment
Note	= Provides additional information to clarify a point in the text.
Important	= Similar to a note but of greater emphasis
⚠	= Attention. Alerts you to a warning or caution in the text.
High Flow Low Vacuum	= high flow, low vacuum
I (On)	= on
O (Off)	= off
	= CE European Union Representative

Operation

1 **Figure 1**

Thoracic Vacuum Regulator

① Mode Selector Switch
② Vacuum Gauge
③ Suction Control Knob
④ Probe/Adapter Port
⑤ Inlet Fitting



CS.18.029, CS.04.005

Equipment Setup

Insert the probe into the vacuum wall outlet. If the regulator is mounted elsewhere, connect a vacuum supply hose between the regulator's probe adapter and the wall outlet.

WARNING ⚠ Connection to pressure sources, even momentarily, could injure the patient or operator and damage the equipment.

Use hospital-supplied suction tubing between the end piece and the collection container, and between the patient port and the patient (minimum inside diameter is 6 mm [0.25 in.]).

An Ohmeda High Flow Suction Filter should be used between the collection container and regulator to prevent contamination of the regulator.

ISO 10079-3 (BS 7259: Part 2, section 5.1.2) states that "the usable volume of the collection container shall not be less than 500 ml."

Suction Filters

Carton of 20	6730-0350-800	Carton of 200	6730-0351-800

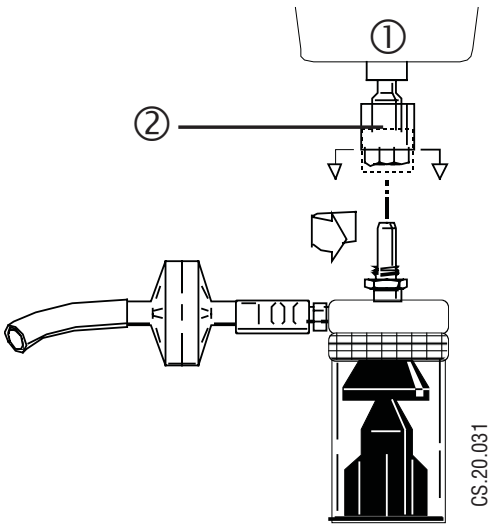
Attaching the Safety Trap

CAUTION ⚠ To help prevent aspirate from entering the regulator as a result of misuse, an Overflow Safety Trap should be attached prior to its use. Aspirate in the regulator may impair its operation. The use of the Overflow Safety Trap and suction filter will help prevent this and extend the life of suction equipment.

2 Figure 2

Trap fitting

1. Raise the sleeve and insert the trap into the regulator fitting.
2. Turn the trap clockwise about one and a half turns to engage the threads. The trap does not need to be screwed tight; an O-ring in the regulator fitting provides a vacuum seal. The trap should rotate freely to allow the desired tubing positioning.
3. Lower sleeve to lock trap in position.



① Regulator

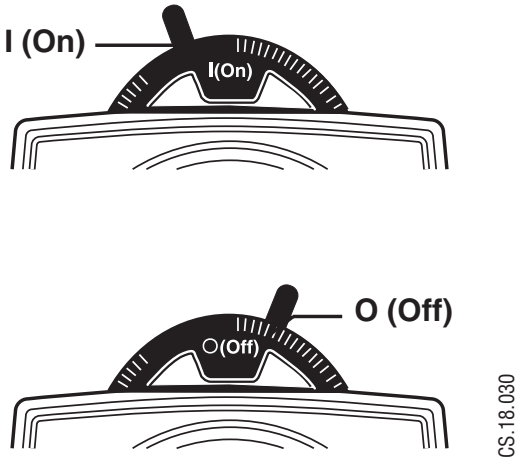
② Sleeve

Mode Selection

3 **Figure 3**

I (On) - Suction can be adjusted with the suction control knob.

O (Off) - No suction is supplied to the patient.

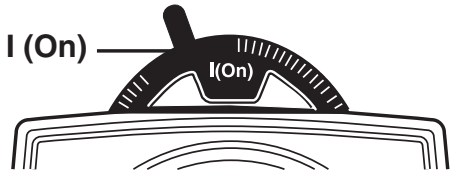


WARNING ⚠ **A positive pressure relief valve in the Thoracic regulator will prevent pressure buildup in the system only if the system is not clamped between the regulator and patient.**

Setting the suction level

4 **Figure 4**

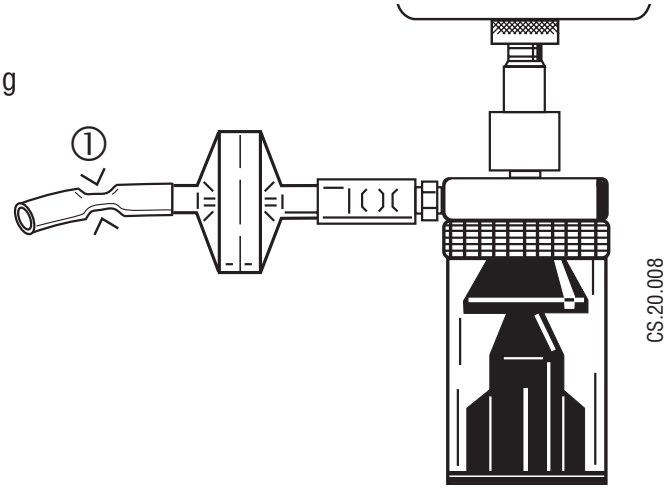
1. Turn the mode selector switch to I (on).



5 **Figure 5**

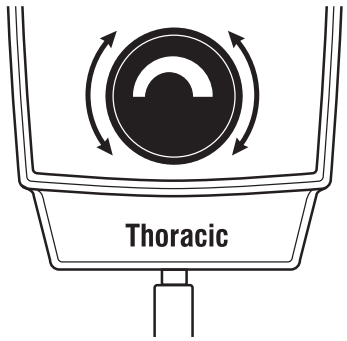
2. Occlude or clamp tubing

   ① Clamp



6 **Figure 6**

3. Rotate the suction control knob until the vacuum gauge indicates the required setting.



WARNING ⚠ The regulator must be occluded when setting the prescribed suction level so that the patient does not receive higher than required suction.

Pre-Use Checkout Procedure

WARNING ⚠ The Pre-Use Checkout Procedure must be performed before using the equipment on each patient. If the regulator fails any part of the Pre-Use Checkout Procedure, it must be removed from service and repaired by qualified service personnel.

All tests must be performed with supply vacuum of 40 kPa (-300 mm Hg) minimum.

1. Turn the mode selector switch to O (Off).

   Rotate the suction control knob one full turn clockwise (increase).

   Clamp tubing to occlude the fitting port. The gauge needle should not move.
2. Turn the mode selector switch to I (On).

   Rotate the suction control knob fully anti-clockwise (decrease).

   Clamp tubing. The gauge needle should not move.
3. Clamp tubing and increase the suction to 35 cm H_2O

   Slowly open and close the clamped tubing to create various flow rates through the regulator. Check that the suction level is maintained when the tubing is clamped.

   Rotate the suction control knob fully clockwise (increase) to check that the relief valve activates between -50 to -60 cm H_2O. When the relief valve opens a “venting” sound will be produce.

   Reduce the suction to zero and set the mode selector switch to O (Off).

Patient Setup

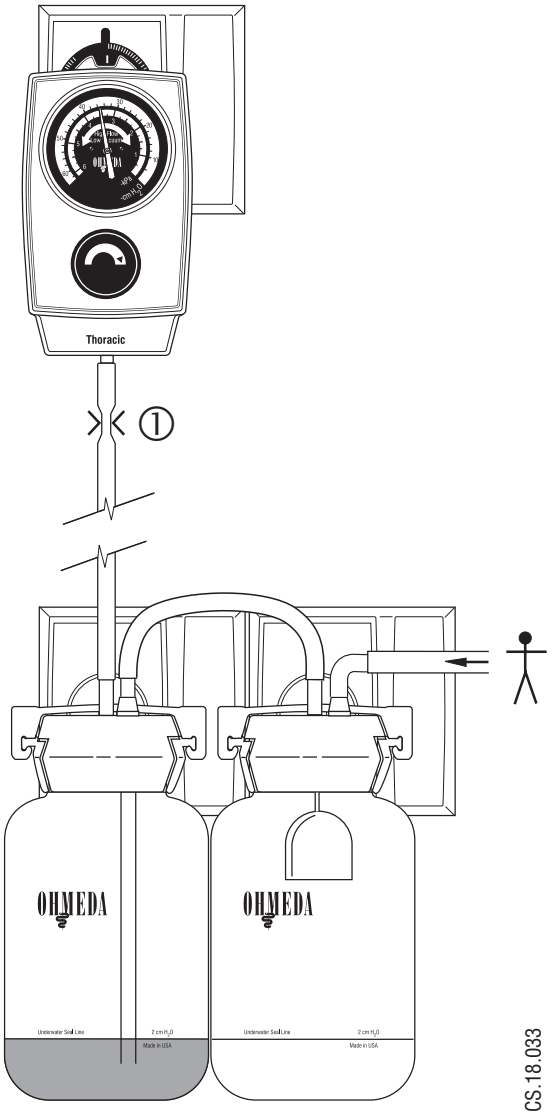
1. Make sure the Pre-Use Checkout Procedure has been performed.

7 **Figure 7**

Setup with reusable collection system

2. Turn the mode selector switch to I (On) and clamp tubing.

① Clamp



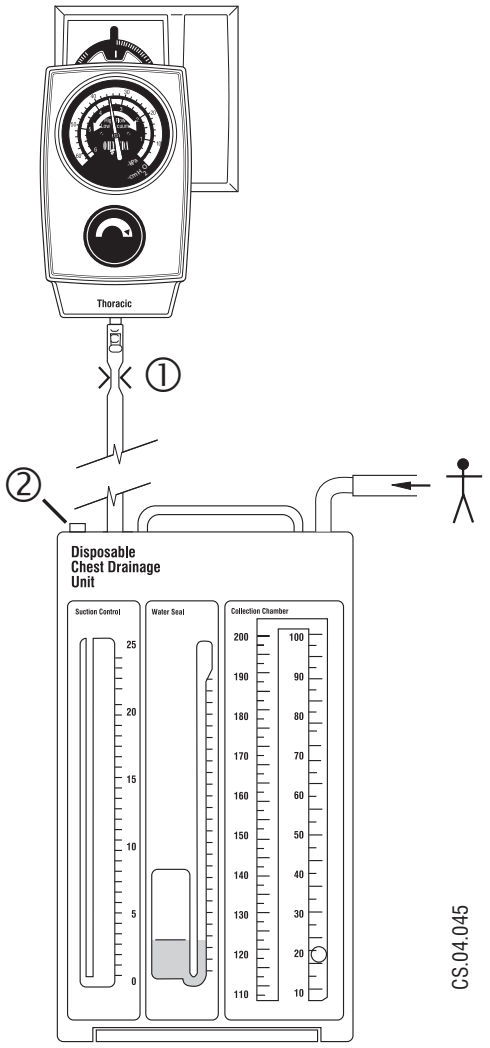
8 **Figure 8**

Setup with disposable collection system

3. Turn the mode selector switch to I (On), clamp tubing and occlude vent on disposable collection system.

   ① Clamp

   ② Occlude vent



WARNING ⚠ When using a disposable collection system, the atmospheric vent at the top of the suction control chamber must be occluded for proper suction regulation with the Thoracic regulator.

Important: Once the atmospheric vent is occluded, the Thoracic regulator controls vacuum level regardless of the presence or amount of water in the suction control chamber.

4. Set the prescribed suction level.

WARNING ⚠ The regulator must be occluded when setting the prescribed suction level so that the patient does not receive higher than required suction.

Important: Subtract 2 cm water seal amount from the level set on the regulator gauge to determine the total suction level applied to the patient.

WARNING ⚠ Continuing to rotate the suction control knob past the point where the relief valve opens may result in suction levels higher than the preset relief pressure.

5. Turn the mode selector switch to O (Off).

6. Attach tubing to the vacuum port of the collection container.
7. Connect the regulator to a reusable water seal or a disposable system with a water seal.

WARNING ⚠ **A water seal must be used with the thoracic regulator to prevent air from entering the pleural cavity, and to indicate the presence of air leaks in the lungs and/or the collection system.**

8. With reusable collection systems, connect the water seal to the vacuum port of the collection container.
9. Attach the patient tubing to the patient port of the collection container.
10. Turn the mode selector switch to I (on).
11. Clamp the patient tubing.

After a brief period the bubbling in the water seal should stop.

WARNING ⚠ **With the patient tubing occluded, all the bubbling in the water seal should stop. If bubbling does not stop, check all connections to eliminate leaks.**

12. Release the clamp on the patient tubing.

WARNINGS ⚠ **When a leak free collection system connected to a patient is turned on, and after initial air in the system is eliminated, only patient air will produce bubbles in the water seal.**

⚠ **Do not clamp the tubing between the patient and the collection bottle; a pressure build up in the catheter and tubing will result.**

Cleaning

Cleaning the regulator is recommended as a standard procedure after each use.

Wipe all exterior surfaces with a solution of water and mild detergent.

Should misuse occur resulting in accidental flooding of the regulator, the regulator may be sterilized using ethylene oxide (ETO). See section 5 of the regulator service manual. After sterilization follow the service checkout procedures in section 8 of the regulator service manual.

WARNINGS ⚠ **After patient use, regulators may be contaminated. Handle in accordance with your hospital's infection control policy.**

⚠ **Clean and sterilize all suction equipment before shipment to ensure transportation personnel and service personnel are not exposed to any hazardous contamination.**

⚠ **Following sterilization with ethylene oxide, parts should be quarantined in a well ventilated area to allow dissipation of residual ethylene oxide gas absorbed by the material. Aerate parts for 8 hours at 54°C (130°F).**

CAUTION ⚠ Do not steam autoclave or liquid sterilize the regulator. Severe impairment to the operation of the regulator will result.

Troubleshooting

If the regulator does not operate and you have performed the Pre-Use Checkout Procedure, the following procedures may be used to attempt to correct the problem.

Problem	Possible Cause	Remedy
No suction	Mode selector is in the O (Off) position or between positions	Switch to I (On)
	Leak in system	Check lid is secure on the collection container
		Check tubing connections Check tubing and replace if necessary
	Atmospheric vent open (disposable only)	Occlude vent
	Suction control knob at full decrease	Rotate the suction control knob in the increase direction (clockwise)
Regulator makes loud “venting” sound	Limit of negative pressure relief valve is reached	Clamp patient tubing and rotate suction control knob in the decrease direction (anti-clockwise)

Important: If the above actions do not correct the problems or other problems exist, refer servicing to qualified service personnel.

Warranty

This Product is sold by Ohio Medical under the warranties set forth in the following paragraphs. Such warranties are extended only with respect to the purchase of this Product directly from Ohio Medical or Ohio Medical's Authorized Dealers as new merchandise and are extended to the first Buyer thereof, other than for purpose of resale.

For a period of thirty-six (36) months from the date of original delivery to Buyer or to Buyer's order, but in no event for a period of more than two years from the date of original delivery by Ohio Medical to an Ohio Medical Authorized Dealer, this Product, other than its expendable parts, is warranted to be free from functional defects in materials and workmanship and to conform to the description of the Product contained in this operation manual and accompanying labels and/or inserts, provided that the same is properly operated under conditions of normal use, that regular periodic maintenance and service is performed and that replacements and repairs are made in accordance with the instructions provided. This same warranty is made for a period of thirty (30) days with respect to the expendable parts. The foregoing warranties shall not apply if the Product has been repaired other than by Ohio Medical or in accordance with written instructions provided by Ohio Medical, or altered by anyone other than Ohio Medical, or if the Product has been subject to abuse, misuse, negligence, or accident.

Ohio Medical's sole and exclusive obligation and Buyer's sole and exclusive remedy under the above warranties is limited to repairing or replacing, free of charge, at Ohio Medical's option, a Product, which is telephonically reported to the nearest Ohio Medical Regional Service Office and which, if so advised by Ohio Medical, is thereafter returned with a statement of the observed deficiency, not later than seven (7) days after the expiration date of the applicable warranty, to the designated Ohio Medical Service Office during normal business hours, transportation charges prepaid, and which, upon Ohio Medical's examination, is found not to conform with the above warranties. Ohio Medical shall not be otherwise liable for any damages including but not limited to incidental damages, consequential damages, or special damages.

There are no express or implied warranties which extend beyond the warranties hereinabove set forth. Ohio Medical makes no warranty of merchantability or fitness for a particular purpose with respect to the product or parts thereof.

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